DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2014

Bahadir USA Corporation
Mr. Ismail Kilic
President
275 West Hoffman Avenue
Lindenhurst, NY 11757

Re: K131407
Trade/Device Name: Bahadir Sterilization Containers
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wraps, Trays, Containers
Regulatory Class: II
Product Code: KCT
Dated: August 1, 2014
Received: August 4, 2014

Dear Mr. Kilic:

This letter corrects our substantially equivalent letter of August 12, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), **please** contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use
(Page 1 of 3)

510(k) Number: K131407

Device Name: Bahadir Sterilization Containers

Indications For Use:
Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized for Immediate Use and/or Pre Vacuum Sterilization. Pre Vacuum sterilized devices may be stored in protective storage (temperature, humidity, air filtration etc. controlled hospital storage room conditions) for up to 6 months provided integrity of container is not compromised.

Bahadir Pre Vacuum sterilization containers may be stacked during storage, one on top of one another, the heavier container being on the bottom. Pre Vacuum sterilization containers may be stacked up to 18 inches during the sterilization process with no more than THREE containers as part of the 18" maximum configuration. Containers are marked as to their height to facilitate this process.

- 3 containers **MAXIMUM** can be stacked.
- Stacked containers may not exceed a **maximum of 18 inches**

Immediate Use only intended for non-stacked configurations during the sterilization process.

The devices included in this submission are to be used with a pre-vacuum, three pulse standard cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes or Immediate Use sterilization.

The devices (natural aluminum color containers with colored lids as follows: green, yellow/golden orange, red, deep black and natural aluminum) subject to this submission are as follows:

Flat Size Y310.05A
Flat Size Y310.08A
Flat Size Y311.08A

Mini Size Y410.04A
Mini Size Y410.07A
Mini Size Y410.10A
Mini Size Y411.04A
Mini Size Y411.07A
Mini Size Y411.10A

Dental Size Y510.04A
Dental Size Y510.06A
Dental Size Y510.08A
Dental Size Y510.10A
Dental Size Y510.13A
Dental Size Y511.04A
Dental Size Y511.06A
Dental Size Y511.08A
Dental Size Y511.10A
Dental Size Y511.13A

Full size Y110.10W
Full size Y111.10W
Full size Y110.13W
Full size Y111.13W
Full size Y110.15W
Full size Y111.15W
Full size Y110.20W
Full size Y111.20W
Full size Y111.26W
Wide size Y110.62W
Wide size Y110.68W
Wide size Y111.62W
Wide size Y111.68W

¾ size Y210.10W
¾ size Y210.13W
¾ size Y210.15W
¾ size Y211.10W
¾ size Y211.13W
¾ size Y211.15W

½ size Y310.10W
½ size Y310.13W
½ size Y310.15W
½ size Y310.20W
½ size Y310.26W
½ size Y311.10W
½ size Y311.13W
½ size Y311.15W
½ size Y311.20W
½ size Y311.26W

Indications for Use

The Containers have been validated for sterilization of instrument load weights shown below, and may include in this max load weight up to 2 instruments with lumens no smaller than 1 mm in diameter and no longer than 300 mm in length for the Full Size, ¾ Size, and Wide Body Containers, and no smaller than 1 mm in diameter and no longer than 200mm in length for the Half Size, Mini, Flat, & Dental Containers.

The maximum load weights for the Sterilization Containers which are the subject of this premarket notification are as follows:

Maximum Recommended Load (including basket and contents)

Model	Dimensions (mm)	LBS.
1/1 Size Container	580X280X100	24.75
	580X280X135	24.75
	580X280X150	24.75
	580X280X200	24.75
	580X280X260	24.75
3/4 Size Container	465x280x100	12.5
	465x280x135	12.5
	465x280x150	12.5
1/2 Size Container	285x280x100	9.25
	285x280x135	9.25
	285x280x150	9.25
	285x280x200	9.25
	285x280x260	9.25
Wide Body Container	600x400x120	24.75
	600x400x180	24.75
Flat Container	285x280x55	9.25
	285x280x85	9.25
Mini Container	300x140x40	6.0
	300x140x70	6.0
	300x140x100	6.0
Dental Container	310x190x40	9.25
	310x190x65	9.25
	310x190x130	9.25

Indications for Use

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Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K131407

510(k) Summary (as required by 21 CFR 807.92(c))

Manufacturer Name and Address

Bahadir USA Corp.
275 West Hoffman Avenue
Lindenhurst, NY 11757
Contact: Ismail Kilic
Tel: 631-608-8522

Submitter / Contact Person

Bahadir USA Corp.
275 West Hoffman Avenue
Lindenhurst, NY 11757
Contact: Ismail Kilic
Tel: 631-608-8522
Email: info@bahadirusa.com

Date Prepared

August 12, 2014

Name of Device

BAHADIR STERILIZATION CONTAINERS

Classification Name

Sterilization Wraps, Trays, Containers
Class II – KCT

Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Tray

Predicate Devices

Bahadir – K112090
Bahadir– K102146
Aesculap – K053389
Sklar – K091720

K131407

Intended Use:

Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized for Immediate Use and/or Pre Vacuum Sterilization. Pre Vacuum sterilized devices may be stored in protective storage (temperature, humidity, air filtration etc. controlled hospital storage room conditions) for up to 6 months provided integrity of container is not compromised. Bahadir Pre Vacuum sterilization containers may be stacked during storage, one on top of one another, the heavier container being on the bottom. Pre Vacuum sterilization containers may be stacked up to 18 inches during the sterilization process with no more than THREE containers as part of the 18" maximum configuration. Containers are marked as to their height to facilitate this process.

- 3 containers **MAXIMUM** can be stacked.
- Stacked containers may not exceed a **maximum of 18 inches**

Immediate Use only intended for non-stacked configurations during the sterilization process. Immediate Use sterilized devices cannot be stored.

The devices included in this submission are to be used with a pre-vacuum, three pulse standard cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes or Immediate Use sterilization.

DESCRIPTION OF DEVICE

The devices (natural aluminum color containers with colored lids as follows: green, yellow/golden orange, red, deep black and natural aluminum) subject to this submission are as follows:

Flat Size Y310.05A
Flat Size Y310.08A
Flat Size Y311.08A

Mini Size Y410.04A
Mini Size Y410.07A
Mini Size Y410.10A
Mini Size Y411.04A
Mini Size Y411.07A
Mini Size Y411.10A

Dental Size Y510.04A
Dental Size Y510.06A
Dental Size Y510.08A
Dental Size Y510.10A
Dental Size Y510.13A
Dental Size Y511.04A
Dental Size Y511.06A
Dental Size Y511.08A
Dental Size Y511.10A

Full size Y110.10W
Full size Y111.10W
Full size Y110.13W
Full size Y111.13W
Full size Y110.15W
Full size Y111.15W
Full size Y110.20W
Full size Y111.20W
Full size Y111.26W
Wide size Y110.62W
Wide size Y110.68W
Wide Size Y111.62W
Wide Size Y111.68W

¾ size Y210.10W
¾ size Y210.13W
¾ size Y210.15W
¾ size Y211.10W
¾ size Y211.13W
¾ size Y211.15W

½ size Y310.10W
½ size Y310.13W
½ size Y310.15W
½ size Y310.20W
½ size Y310.26W
½ size Y311.10W
½ size Y311.13W
½ size Y311.15W
½ size Y311.20W
½ size Y311.26W

The devices are composed of anodized aluminum alloy with lid colors as follows: green, yellow/ golden orange, red, black and natural aluminum.

K131407

Indications For Use:

Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized for Immediate Use and/or Pre Vacuum Sterilization. Pre Vacuum sterilized devices may be stored in protective storage (temperature, humidity, air filtration etc. controlled hospital storage room conditions) for up to 6 months provided integrity of container is not compromised. Bahadir Pre Vacuum sterilization containers may be stacked during storage, one on top of one another, the heavier container being on the bottom. Pre Vacuum sterilization containers may be stacked up to 18 inches during the sterilization process with no more than THREE containers as part of the 18" maximum configuration. Containers are marked as to their height to facilitate this process.

The Containers have been validated for sterilization of up to 2 instruments with lumens no smaller than 1 mm in diameter and no longer than 300 mm in length for the Full Size, ¾ Size, and Wide Body Containers, and no smaller than 1 mm in diameter and no longer than 200mm in length for the Half Size, Mini, Flat, & Dental Containers. Pre Vacuum sterilization containers may be stacked up to 18 inches during the sterilization process with no more than THREE containers as part of the 18" maximum configuration. Containers are marked as to their height to facilitate this process

- 3 containers **MAXIMUM** can be stacked.
- Stacked containers may not exceed a **maximum of 18 inches**

Immediate Use only intended for non-stacked configurations during the sterilization process.

The maximum load weights for the Sterilization Containers which are the subject of this premarket notification are as follows:

Maximum Recommended Load (including basket and contents)

Model	Dimensions (mm)	LBS.
1/1 Size Container	580X280X100	24.75
	580X280X135	24.75
	580X280X150	24.75
	580X280X200	24.75
	580X280X260	24.75
3/4 Size Container	465x280x100	12.5
	465x280x135	12.5
	465x280x150	12.5
1/2 Size Container	285x280x100	9.25
	285x280x135	9.25
	285x280x150	9.25
	285x280x200	9.25
	285x280x260	9.25
Wide Body Container	600x400x120	24.75
	600x400x180	24.75
Flat Container	285x280x55	9.25
	285x280x85	9.25
Mini Container	300x140x40	6.0
	300x140x70	6.0
	300x140x100	6.0
Dental Container	310x190x40	9.25
	310x190x65	9.25
	310x190x130	9.25

Comparison to Predicate Devices

The containers are the identical design to the predicates. The differences are the dimensions (sizes), addition of colored lids, addition of Pre Vacuum and Immediate Use Sterilization, validation for stacking and use with air and power driven instruments.

Feature	**Bahadir Subject Device**	**Bahadir K102146**	**Bahadir K112090**	**Aesculap Sterilcontainer K053389**	**Sklar Sklarlite K091720**
Intended Use	Intended for use in hospitals and healthcare facilities to contain medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, and air power driven instruments using high vacuum steam sterilizers for 270 F for 4 minutes with 20 minutes dry time, Immediate Use/Pre-Vacuum steam sterilization.	Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices using steam sterilizers. Sterilized devices may be stored and transferred in container. To be used with a pre-vacuum cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes.	Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers for 270 F for 4 minutes with 20 minutes (minimum) dry time.	Intended to be used to enclose other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and maintain sterility until used. Validated for pre-vac/flash sterilization.	Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers at 270 F for 4 minutes with a 30 minute (minimum) drying time.
Material	Anodized aluminum alloy, stainless steel handles, silicone seal, paper filter lid colors as follows: green, yellow/ golden orange, red, deep black and natural aluminum.	Anodized aluminum alloy, stainless steel handles, silicone seal, paper filter, lid color: natural aluminum	Anodized aluminum alloy, (natural),stainless steel handles, silicone seal, paper filter	Anodized aluminum alloy complete with wired mes baskets and accessory lids. Tamper proof seal, paper filter, lid colors as follows: red, blue, green, gold and natural aluminum	Anodized aluminum alloy with plastic tamper proof seal and to be used with paper filters. Lid colors are as follows: yellow, red, blue, green, black and natural aluminum.
Filter	Paper filter-one time use	Paper filter-one time use	Paper filter-one time use	Paper filter-one time use with Immediate Use sterilization and reusable filter available for pre vacuum sterilization.	Paper filter-one time use
Sterilization Method	Steam	Steam	Steam	Steam	Steam
Configurations / Dimensions	Flat Size: Y310.05A Flat Size: Y310.08A Flat Size: Y311.08A Mini Size: Y410.04A Mini Size: Y410.07A Mini Size: Y410.10A Mini Size: Y411.04A Mini Size: Y411.07A Mini Size: Y411.10A Dental Size: Y510.04A Dental Size: Y510.06A Dental Size: Y510.08A Dental Size: Y510.10A Dental Size: Y510.13A Dental Size: Y511.04A Dental Size: Y511.06A Dental Size: Y511.08A Dental Size: Y511.10A	Full Size Y110.20W Full Size Y110.15W Full Size Y110.13W Full Size Y110.10W 3/4 Size Y210.10W 3/4 Size Y210.13W 3/4 Size Y210.15W 1/2 Size Y310.20W 1/2 Size Y310.15W 1/2 Size Y310.13W 1/2 Size Y310.10W	Full Size Y111.10W Full Size Y111.13W Full Size Y111.15W Full Size Y111.20W Full Size Y111.26W Wide Size Y110.62W Wide Size Y110.68W Wide Size Y111.62W Wide Size Y111.68W ¾ Size Y211.10W ¾ Size Y211.13W ¾ Size Y211.15W ½ Size Y311.10W ½ Size Y311.13W ½ Size Y311.15W ½ Size Y311.20W ½ Size Y311.26W	Full Size Lid JK489 Bottoms: Full Size JK440 Full Size JK441 3/4 Size Lid JK789 Bottoms: ¾ Size JK740 ¾ Size JK741 ¾ Size JK742 ½ Size Lid JK389 Bottoms: ½ Size JK339 ½ Size JK340 ½ Size JK341 ½ Size JK342 ½ Size JK344 Mini Size Lid JK174 Bottoms: Mini JK187 Mini JK188	Full Size 580mmX280mm Mid Size 465mmx280mm Half Size 285mmx280mm

	Dental Size: Y511.13A Full size Y110.10W Full size Y111.10W Full size Y110.13W Full size Y111.13W Full size Y110.15W Full size Y111.15W Full size Y110.20W Full size Y111.20W Full size Y111.26W Wide size Y110.62W Wide size Y110.68W Wide size Y111.62W Wide size Y111.68W 3/4 size Y210.10W 3/4 size Y210.13W 3/4 size Y210.15W 3/4 size Y211.10W 3/4 size Y211.13W 1/2 size Y310.10W 1/2 size Y310.13W 1/2 size Y310.15W 1/2 size Y310.20W 1/2 size Y310.26W 1/2 size Y311.10W 1/2 size Y311.13W 1/2 size Y311.15W 1/2 size Y311.20W 1/2 size Y311.26W				
Perforation	The units included in this submission include perforated and non perforated lids perforated bottoms.	The units included in this submission include perforated lids and non perforated bottoms.	The units included in this submission include perforated lids and non-perforated bottoms.	Units include both perforated and solid, solid bottoms to be used in Pre Vac/Flash sterilizers.	Units include both perforated and non perforated.
Air Permeance	Permits entry of sterilization agent and prevents microbial migration during storage.	Permits entry of sterilization agent and prevents microbial migration during storage.	Permits entry of sterilization agent and prevents microbial migration during storage.	Permits entry of sterilization agent and prevents microbial migration during storage.	Permits entry of sterilization agent and prevents microbial migration during storage.
Intended for reuse	Yes	Yes	Yes	Yes	Yes
Sealed	Yes	Yes	Yes	Yes	Yes
Gasket	Silicone based	Silicone based	Silicone based	Silicone based	Silicone based
Handles	Stainless steel	Stainless steel	Stainless steel	Stainless steel	Stainless steel
Cycle Parameters	Pre-Vac 270 F at 4 minutes, 20 minutes drying time or Immediate Use Sterilization	270 F at 4 minutes 20 minutes drying time.	270 F at 4 minutes 20 minutes drying time.	Steam, Pre Vacuum cycle of 4 minutes at 270 degrees F with a dry time of 15 minutes or Immediate Use sterilization.	Pre Vacuum cycle of 4 minutes at 270 degrees F with a dry time of 30 minutes or Immediate Use sterilization.
Conformance to AAMI ST77	Yes	Yes	Yes	Yes	Yes
Use with cannulized, lumen, and air and power driven instruments	Max of one (1) each air driven instruments(air driven hand pieces) weighing no more than 3 lb and measuring no more than 4" in length; max of one (1) power driven instrument (endoscopy/arthroscopy shaver & saw) weighing no more than 5 lb and measuring no more than 10" in length	No	No	Yes	No

The differences are as follows:

- The dimensions (sizes)
- Addition of colored lids - green, yellow/ golden orange, red, deep black and natural aluminum
- Addition of Immediate Use Sterilization
- Addition of stacking option
- Addition of ability to be used with air and power driven instruments

The above differences were addressed with validation testing and do not affect the safety and effectiveness of the subject device when used as labeled.

Non-Clinical Tests Performed

The subject devices were subjected to sterility testing, performance testing and biocompatibility testing.

Aging Studies:

Six Month Real Time Aging Validation For Dental Containers Report– Test Passed

Six Month Real Time Aging Validation For Aluminum Sterilization Containers Report– Test Passed

Six Month Accelerated Aging Validation & Container Microbial Barrier Integrity Study for Half, Three Quarter & Full Size Container Report– Test Passed

Six Month Accelerated Aging Validation & Container Microbial Barrier Integrity Study for Full and Wide Body Size Container Report– Test Passed

Six Month Accelerated Aging Validation & Container Microbial Barrier Integrity Study for Mini, Flat & Dental Size Container Report– Test Passed

Pre-Vac Sterilization:

Pre-Vac Sterilization Validation for Mini, Dental & Flat Containers Report– Test Passed

Pre-Vac Sterilization Validation for Half, Three-Quarter & Full Size Containers Report – Test Passed

Pre-Vac Sterilization Validation for Wide Body Containers– Test Passed

Microbial Barrier & Air Impermeability:

Air Impermeability Performance after 500 sterilization cycles Report– Test Passed

Investigation of Microbial Barrier Properties Report– Test Passed

Six Month Accelerated Aging Validation & Container Microbial Barrier Integrity Study for Half, Three Quarter & Full Size Container Report – Test Passed

Six Month Accelerated Aging Validation & Container Microbial Barrier Integrity Study for Full and Wide Body Size Container Report – Test Passed

Six Month Accelerated Aging Validation & Container Microbial Barrier Integrity Study for Mini, Flat & Dental Size Container Report – Test Passed

Immediate Use:

Immediate Use Sterilization Validation Summary for Mini, Dental & Flat Containers Report – Test Passed

Immediate Use Sterilization Validation Summary for Half, Three Quarter, Full & Wide Body Size Containers Report– Test Passed

Stacking:

Stacking Validation Full, Wide, Three Quarter & Half Size Containers Report - Test Passed

Stacking Validation For Dental Sterilization Report – Test Passed

Stacking Validation Protocol - ¾ Size Containers – Testing completed and passed

Stacking Validation Protocol Mini Dental Size Containers – Testing completed & passed

Summary

The performance and biocompatibility tests demonstrate that the Bahadir Sterilization Containers are substantially equivalent to the predicate devices.